

Krystexxa® (pegloticase)

When requesting Krystexxa® (pegloticase), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

- Krystexxa® (pegloticase) is indicated for the treatment of chronic gout in individuals refractory to conventional therapy.

Approved Off-label Compendial use

- None

Coverage Guidelines

Chronic Gout

The individual must meet **all** of the following criteria for approval:

- 18 years of age and older
- Does **not** have a diagnosis of glucose-6-phosphate dehydrogenase deficiency
- Diagnosis of chronic gout (hyperuricemia)
- Symptomatic gout with a history of at least 3 gout flares in the previous 18 months or at least 1 gouty tophus or chronic gouty arthritis
- Has a medical contraindication or intolerance to xanthine oxidase inhibitors (e.g., allopurinol and febuxostat), or inadequate response to xanthine oxidase inhibitors (failure to normalize uric acid to less than 6 mg/dL after at least 3 months of xanthine oxidase inhibitor treatment at the maximum medically appropriate dose)

Approval duration: 12 months

Additional Information for Prescribers

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Advise individuals to discontinue any oral urate-lowering agents before starting on Krystexxa® (pegloticase) and not to take any oral urate-lowering agents while on Krystexxa® (pegloticase).
- Anaphylaxis and infusion reactions have been reported to occur during and after administration of Krystexxa® (pegloticase).
- Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported.
- Krystexxa® (pegloticase) should be administered in healthcare settings, and by healthcare providers prepared to manage anaphylaxis and infusion reactions.

- Individuals should be premedicated with antihistamines and corticosteroids.
- Individuals should be closely monitored for an appropriate period of time for anaphylaxis after administration of Krystexxa® (pegloticase).
- Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

References

1. Krystexxa® prescribing information. Lake Forest, IL: Horizon Pharma USA, Inc.: September 2016. https://hzn.azureedge.net/public/KRYSTEXXA_Prescribing_Information.pdf. Accessed April 24, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed April 24, 2017. <https://www.micromedexsolutions.com>